## REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 12, 13 and 14 have been amended to incorporate the limitation of claim 22, specifying that the infant or child has never been affected by asthma disease.

Turning to the Official Action, the Applicants acknowledge with thanks the Examiner's withdrawal of the 102 rejection.

Claims 12-20, 22 and 23 remain rejected under 35 USC 103 as unpatentable over Trieloff for the reasons set forth. This ground of rejection is respectfully traversed.

The Applicants respectfully disagree with the Examiner that the Trieloff document teaches preventive therapy with cetirizine for children ages 1-2 years wherein the onset of asthma has not occurred as stated on page 3 of the Office Action.

On the contrary, in paragraph 2 of the document related to the ETAC study, Trieloff relates to the fact that cetirizine may reduce the incidence of infantile asthma or at least reduce the severity of the condition. This paragraph clearly suggests to the skilled person that the infant or child may already have a history of asthma.

Furthermore, in paragraph 4 of the Trieloff document, conditions of inclusion of children to the study are defined i.e. children ages 1 to 2 years having had atopic dermatitis for a period of at least 4 weeks and having a parent or a sibling suffering from neurodermatitis, asthma or allergic rhinitis. No other condition is mentioned and especially not that the children have never been affected by asthma disease as defined by our claims. Should this have been a requirement for the success of the study, the Trieloff document would certainly have mentioned it.

Therefore, nothing in the Trieloff document will suggest to the skilled person to use a method of preventing the onset of asthma wherein the children have never been affected by asthma disease, or that it would be essential to guarantee the success of the method that the children had never been affected by asthma, as defined by the amended claims 12, 13 or 14.

Moreover, as previously explained, the Trieloff document was an attempt to improve recruitment to the study and contained no result of the study. Consequently, it is clearly non-enabling and no reasonable expectation of success can be shown. The terminology used in this document clearly shows that no one can predict the result of the study with any reasonable degree of certainty. Pharmaceutical chemistry is inherently unpredictable. For example, the following extracts of the English translation of the Trieloff document support this conclusion:

- page 1, paragraph 1: "...preventive therapy with cetirizine...**may** offer protection..."
- page 1, paragraph 2: "...The ETAC study **will** include..."
- page 2, heading: Cetirizine: **possible** preventive therapy
- page 2, paragraph 2: "The current ETAC study **will attempt** for the first time to prevent the "switch" from atopic dermatitis to asthma.
- page 2, paragraph 3: "Pediatricians **still have the chance** to recommend children from their own practice for inclusion of the study".

Accordingly, it is respectfully submitted that the cited reference fails to suggest the successfulness of the claimed methods with a reasonable expectation of success.

Accordingly, favorable reconsideration and allowance is solicited.

Respectfully submitted,

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June 15, 2005